

# Modern concept analysis of failure modes and consequences for quality assurance of products and processes

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**Abstract.** Human needs in certain types of products, in new goods and services are constantly developing, changing, clarifying. To meet these needs, new goods samples are being created, and the products are being improved. Production processes are being developed, new equipment, tools and techniques are being created. New technical solutions, new operations application as well as execution methods can produce constructive errors and dangerous situations both during production and during its exploitation. The Failure Mode and Effects Analysis (FMEA) allows to predict that product lifecycle processes can function not properly. FMEA helps ensure the products and processes quality at the earliest stages of its design. The American approach (AIAG – Automotive Industry Action Group) and the German approach (VDA – Verband der Automobilindustrie) have now been harmonized. In 2019, the FMEA Handbook was published, reflecting the new FMEA implementation concept. Experience has emerged with a new approach. The work considers the possibilities of applying a new approach in the conditions of Russian companies, which allows to find new technical solutions.

## 1. Introduction

Reliable trouble-free operation of the products produced by the enterprise is a solid basis for the company's development and a good basis for further progress in its production activities. Many market participants create new products and services based on the thorough investigation, analysis and deep understanding of their current and future consumers' requirements and expectations [1]. Moreover, the most successful enterprises and organizations aim to ensure the high quality of newly developed products and their production processes at the earliest design stages, long before the batch production starts [2,3,4].

All the new equipment development and production stages affect the products quality, its relevance, level of reliability, deliveries timeliness implemented by the company [5]. The first part consists of the technical solution search and selection. Then, the construction development, design and design documentation production follow in sequence. Various inaccuracies, deviations, errors, typos and other defects can occur at each stage. The experience of creating new products shows that often the smallest deviations, which seem to be 'nothing', can lead to serious failures, refusals, accidents. Therefore, when planning the parameters of future products, choosing technical solutions, it is useful to identify their potential 'weak points' as earlier as possible. This will allow to proactively develop and improve the new design.



By designing new production processes, individual operations, it is important to explore the design options for the new products production and, if it is necessary, to plan and to implement the preventive actions. Warning is the action taken to correct the cause of a potential non-conformity or other potentially dangerous situation [6]. This approach allows timely detection of potential deviations, failures, refusals of mechanisms and equipment, in the machine-tool attachment behavior. Similarly, it is possible to provide inaccuracies, errors, omissions in the employees' actions and to build production processes in such a way as to protect the company from the appearance of situations that can produce inappropriate products.

## 2. Materials and methods

To solve such problems regularly in 1949, the national standard MIL-STD-1629 'Procedures for Performing a Failure Mode, Effects and Criticality Analysis' was developed and put into operation in the United States. This approach application helped to prevent and avoid many accidents and incidents with military products. The military products reliability has been significantly improved. The automobile assembly companies' representatives drew attention to this phenomenon. Their products are directly related to consumer safety. The fact is that in the automobile industry there are repeated and even mass failures of sold cars. This forces auto-assembly companies to withdraw large quantities of cars (from sellers and buyers) to eliminate the inconsistencies causes, resulting in significant financial losses. In 2014, for example, the car manufacturer Mazda recalled 42.000 cars worldwide due to the failure of the fuel system [7]. In 2018, Toyota decided to recall about 1.7 million cars (including 84.000 cars in Russia), due to possible airbag faults [8]. The failure prevention technique application could have a tangible economic effect in these situations.

So in 1993 a reference guide 'Potential Failure Mode and Effects Analysis' was developed and published (FMEA) by the Automotive Industry Action Group (AIAG) specialists for the US automotive industry and its suppliers. [9] It helped to identify a significant proportion of future problems and study them before serial production began. This significantly reduced business losses in subsequent periods.

The method is logical, understandable and easy to use [10, 11]. It is therefore internationally recognized and widely distributed in many countries in the world in the production types variety. The method is constantly being improved on the basis of empirical data and normative documents changes. The FMEA fourth edition is currently used [12]. The FMEA approach is included in the risk management toolbox [13, 14].

The proposed methodology makes it possible to predict with a high reliability level adverse events and situations of the product possible inappropriate functioning during the life cycle. The FMEA approach application in production practice helps to ensure the future products high quality and reliability, as well as the high quality of new values creation processes at the earliest (development) stages, long before the product is released. Exactly this fact explains the widespread the FMEA approach using for analyzing new design, technology and organizational solutions. Similar approaches are used to analyze risks in the development of management decisions.

It is important to understand that carrying out FMEA in an organization is always a team creative work [3]. Its important component is the application of the A. Osborn's brainstorming method [15]. Brainstorming is an effective way to solve problems by stimulating creative people activity, in which participants in the team work are invited to offer as many options as possible to solve the identified problems including solutions of the most unexpected and fantastic [2, 11, 15]. Conducting a brainstorming session creates a collective creativity atmosphere for the participants and helps the team to realize a synergistic effect during the construction (or research process) discussion. Synergistic effect is considered in the understanding of potential problems, deviations, refusals and other adverse events in the implementation of the technical solution in practice. Exactly the synergy of knowledge and experience of the team participants provides the completeness, reliability and objectivity of the results of such analysis.

The technique FMEA has a high foresight potential. For reusable spaceship, the Shuttle the hidden possibility of a start-up accident in certain weather conditions was identified during analyzing the various external factors on systems impact. In order not to change flight plans the report was ignored. As a result, the accident occurred (according to a scenario predicted by specialists) [16].

The FMEA technique is applied:

- in the analysis of new technical solutions, new system designs, new constructions or modifications;
- when using a known construction, a known technical solution in the new conditions of use and operation;
- when training of new processes (operations) or applying a well-functioning process (operation) in new conditions, to solve new problems;
- in the analysis of designed systems and other similar situations.

A team of specialists (designers, technologists, direct labour, assemblers, testers) is formed to carry out the analytical research. This group must have a good understanding of the design various aspects and its future functioning. In specific projects, other important experts may be engaged for discussion. The team consists of 5–9 participants. It is only with such participants amount the synergy effect can be realized in the discussion.

Debates and fierce disputes are not allowed during the discussions. It is proposed only to analyse, discuss, develop, supplement various situations that may arise in production and during operation, but not necessarily. It is important that each team member has the opportunity to express his or her own opinion.

During the work, the team consistently considers, examines the following questions:

1. What unforeseen, unplanned, unexpected events can happen to the subject during its regular functioning? What kind of failures, refusals may appear?
2. What are the consequences of each of the unplanned events/refusals may appear?
3. What are the reasons that can lead to each of the unplanned events/refusals?

At the same time, it is important to bring the discussion to a concrete outcome. Record clearly defined results. As the discussion results, the team draws up a list of potentially possible adverse events/failures. 'Base of such events/failures' is generated. Then each of these events is examined in terms according to the consequences that can be caused by the events. A list of possible consequences for each event is being compiled. The next step is to investigate the reasons that may cause these adverse events. A list of reasons for possible adverse events is being compiled.

Next, a quantitative assessment is made of possible events. Now the team of specialists must be in a different status. The team must assess all predicted events according to the technique described in [9, 12].

For each possible adverse event/refusal, an event consequences severity assessment is required. The appropriate corresponding characteristic is called 'significance' and is denoted by the symbol S. Tables have been developed for quantification. The significance value of S can take integer values from 1 to 10. Each member of the team gives his or her knowledge and practical experience-based opinion. The arithmetic mean of all scores is taken as the total result of the evaluation.

As the assessment result, a possible adverse event from each consequence is assigned a value S. For further analysis, the highest estimate of the S significance is taken as the considered event effects severity value.

Similarly, the occurrence probability of the reason that may cause the event is evaluated. This value is called 'occurrence' and denotes O symbol. An assessment is also being made of the ability to timely see the situation and prevent the consequences adverse development. The corresponding characteristic is called 'detection' and is denoted by the symbol D. The values of the parameters O and D can vary discretely between 1 and 10. The value tables in the FMEA Manual [12] have also been developed for their evaluation.

The team's work result is the priority risk number determination (PRN) [9,12] for each possible adverse event.

$$PRN = S \cdot O \cdot D \quad (1)$$

When predicting potentially dangerous events, a large number of potential problems may be identified. But it is impossible to deal with all issues at the same time. The PRN value is used to decide on the order of the corresponding warning actions development. The PRN value reflects the relative importance of each situation in its potential hazard terms. The higher the PRN value is, the higher is the situation risk in comparison with others.

Using the obtained PRN values, designers can plan and carry out activities to improve the structures even before making the prototypes. In practice, this possibility saves time considerably. Similarly, technologists can explore new operations and technology chains before they are organized, which also saves resources. First of all, situations with high PRN values are considered. Then with medium and small value are taking into consideration. From experience, it has been proposed to set the boundary PRN value to 120. It is considered that events with lower PRN values can be ignored.

In the German automotive industry, Verband der Automobilindustrie (VDA) developed its own approach to predicting potentially dangerous, emergency situations. Two approaches to FMEA implementation have now been agreed upon. In 2019, as the joint work result of American and German specialists, FMEA Handbook [17] was prepared and published, which reflects the new FMEA concept implementation. This document was published on June 2019. It reflects the current level of risk analysis understanding in the automotive industry.

### 3. Results and discussion

The method is described as the seven steps sequence [17]:

1. Preparation and planning of actions.
2. Analysis of the structure and interaction of the elements.
3. Analysis of the structure and impact of functions.
4. Analysis of the structure refusals.
5. Quantitative risk assessment.
6. Improving design, process, system.
7. Documenting the results of work.

In content terms, these steps largely coincide with the traditional approach to the potentially dangerous events analysis [18].

Criteria for determining the design and process FMEA significance are determined. In particular, the FMEA should focus on the buyer requirements, as well as other interested parties. For the FMEA process, the significance criteria are focused on the producer requirements.

An important change in the methodology was the complete rejection of the PRN value calculation (as the p multiplication of the S, O, D parameters). Instead of such calculation, it is proposed to use special tables. They determine the actions (AP) priority depending on the parameters S, O, D combination. The approach to quantification of the parameters themselves remains unchanged.

It is proposed to use three levels of priority actions (AP) to prevent the product or process failures: high (H), medium (M) and low (L).

- 1) high level – actions required,
- 2) medium level – actions recommended,
- 3) low level – actions can be taken.

In other words, if the AP value is high, improvement actions are mandatory. At medium level - improvement actions are necessary and useful. If the level is low, improvement actions are recommended.

This approach changes the decision-making tactics of FMEA.

Three-level priority separation formalizes the necessary steps algorithm but makes it difficult to choose the specific actions direction. Of the many possible equivalent situations due to the combination of parameter values (S, O, D), it is difficult to build a warning actions sequence.

The absence of an PRN value estimate may lead to additional rating votes on the questions: ‘What is more important and where to start improvements’? The discussions on these issues increases the situation uncertainty. This can lead to mistakes and authoritarian decisions with high risks.

In general, the usefulness of the changes made in FMEA will be assessed objectively after learning from the new approach.

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